

REMARKS

I. Preliminary Remarks

In an Office Action dated September 28, 2006 (the "9/06 Office Action"), Claims 1-28 were pending and under examination. In the 9/06 Office Action, all claims were subject to a requirement for restriction. In their response to that Office Action, Applicants provisionally chose Group II, Claims 2, 4-8, 13-14, 16 and 18 (partially). Claims 1, 3, 9-12, 15, 17, 18 (partially), and 19-28 were withdrawn, with traverse and without prejudice in an effort to favorably advance prosecution of the present application.

In an Office Action dated January 23, 2007 (the "1/07 Office Action"), Groups I and II were rejoined, and Claims 1-18 were examined on merits. Claims 19-28 were withdrawn.

In the current Office Action (the "9/07 Office Action"), the claims are again subject to a requirement for restriction, and are divided into four groups. Applicants provisionally choose Group II, Claims 2, 4-8, 13, 14, and 16, drawn to a polymorph form (I) of a compound of formula I classified in various subclasses of classes 514 and 548. Claims 1, 3, 9-12, 15, 17, 18, and 19-28 are withdrawn, with traverse and without prejudice in an effort to favorably advance prosecution of the present application. Applicants reserve the right to petition for rejoinder should the circumstances allow, or to pursue the subject matter of the withdrawn claims in a divisional application. However, reconsideration and withdrawal of the restriction requirement are solicited for the reasons set out below.

This Response addresses the Examiner's restriction requirement. Applicants therefore respectfully submit that the present application is in condition for examination on the merits. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed with a one-month extension of time. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Remarks/Arguments

In the 9/07 Office Action, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following four separate and distinct inventions:

- I. Claims 1, 3, 9-12, 15, 17, and 18 are drawn to a polymorph form (II) of a compound of formula I classified in various subclasses of classes 514 and 548.
- II. Claims 2, 4-8, 13, 14, and 16 are drawn to a polymorph form (I) of a compound of formula I classified in various subclasses of classes 514 and 548.
- III. Claims 19-28 are drawn to methods of modulating catalytic activity of a protein kinase, methods of treating and preventing every protein kinase related disorder, and methods of treating and preventing various types of cancers, using a polymorph form (II) of a compound of formula I, classified in various subclasses of class 514.
- IV. Claims 19-28 are drawn to methods of modulating catalytic activity of a protein kinase, methods of treating and preventing every protein kinase related disorder, and methods of treating and preventing various types of cancers, using a polymorph form (I) of a compound of formula I, classified in various subclasses of class 514.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group II, Claims 2, 4-8, 13, 14, and 16, drawn to a polymorph form (I) of a compound of formula I, classified in various subclasses of classes 514 and 548. Applicants conditionally withdraw Claims 1, 3, 9-12, 15, 17, 18, and 19-28 with traverse and without prejudice.

Applicants respectfully suggest that claim 18 should be included partially in Groups I and II, because this claim was amended in Applicants' response to the 1/07 Office Action to include "one of claims 1 or 2." Also, Applicants respectfully suggest that Group IV should be drawn to "using a polymorph form (I) of a compound of formula I" (not of formula II).

Pursuant to 37 CFR 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are
claimed in one application, the Commissioner may require
the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing

of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" enough so as to justify the restriction requirement.

As stated by the Examiner: "Inventions I and II relate to structurally different polymorphs of a compound of formula I, as demonstrated by the different set of X-ray diffraction spectrum peaks of Claims 3 and 4. Though polymorph forms I and II both relate to a compound of formula I, they are patentably distinct inventions, since a reference anticipating one polymorphic form (e.g. polymorph I) would not anticipate nor render the other polymorphic form (e.g. polymorph II) obvious." Applicants respectfully submit that while the polymorphs exhibit different PXRD patterns, they are not unrelated. They are related in that they are different forms of a solid phase of the same substance: 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-pyrrolidin-1-yl-ethyl)-amide. As stated in the specification, "Polymorph" refers to a solid phase of a substance, which occurs in several distinct forms due to different arrangements and/or conformations of the molecules in the crystal lattice. A polymorph may also be defined as different unsolvated crystal forms of a compound. Polymorphs typically have different chemical and physical properties..." Thus, polymorphs of a substance have the same molecular structure but different chemical and physical properties. A reference anticipating one polymorph form would certainly anticipate another polymorph form.

In addition, for the Groups to be unrelated, it must be shown that "they are not disclosed as capable of use together." However, in the specification, it is stated: "In the preferred embodiments of the present invention, pure, single polymorphs as well as mixtures comprising two or more different polymorphs are contemplated...." Thus, although polymorphs may have and may be distinguished by different physical, chemical, or mechanical properties, the polymorph I and polymorph II forms are related in that they are different forms of a solid phase of the same substance, and are disclosed as being capable of use together. (see paragraphs 0024 through 0028, inclusive, for complete discussion)

The courts have recognized that it is in the public interest to permit Applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl 456 F.2d 658, 666, 117 U.S.P.Q. 250,256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

In addition, this restriction is improper because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. According to MPEP § 803, the Examiner can only restrict patentable distinct inventions when (1) the inventions are independent or distinct as claimed; and (2) where there is a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. Groups I-IV are all directed to similar subject matter. In fact, all four groups are directed to the same class (class 514). A search in this case would be organized by molecular structure and/or the name of the compound. It would not be by crystal structure or x-ray diffraction patterns. Therefore, it is respectfully submitted that it would not constitute undue burden for the claims of all the groups to be maintained in a single application and for all the groups to be examined together. In particular and at a minimum, Applicants respectfully request that Groups I and II be rejoined. In a similar manner, Applicants respectfully request that Groups III and IV be rejoined.

It is respectfully submitted that prosecution of all of these groups of claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice. Applicants further respectfully suggest that in view of the continued increase of official fees and the potential limitation of Applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous

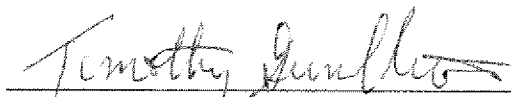
Application No. 10/776,337
Docket No. PC28117A
Filing Date: 2/12/2004

prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

III. Conclusion

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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Date: November 1, 2007

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